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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,836	11/17/2000	Justin R. Fallon	BURF-P01-006	6928

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,836

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

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-- Th MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 15-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 4, 7 and 11-13 have been amended as requested in the amendment of Paper No. 20, filed on December 16, 2002. Claims 1-52 are pending in the instant application.

Claims 15-52 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Claims 1-14 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 16, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 1-6 and 9-14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 4 of paper No. 17.

Claims 1-6 and 9-14, as amended, are directed to methods employing biglycan or a protein having an amino acid sequence with 80%, 90% or 95% identity to a biglycan of SEQ ID

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NO: 9, or a portion of biglycan and possessing DAPC-stabilizing activity. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims.

Applicant submits that “the correlation between structure and function [...] is now present in the claimed genus, and no structurally or functionally unrelated polypeptides fall within the scope of the amended claims” (page 6, first paragraph of the Response). This has not been found to be persuasive because the presented amendment of claim 1 (“being at least 80%, 90% or 95% identical to SEQ ID NO: 9, or portion thereof”) does not satisfy written description of physical or chemical characteristics of the proteins utilized in the claimed method. The instant specification fails to provide relevant guidance or teaching regarding structure and function of the recited biglycan molecules and presents only a single example of SEQ ID NO: 9 and no information regarding a complete structure of those polypeptides which are biglycan or a protein having an amino acid sequence with 80%, 90% or 95% identity to SEQ ID NO: 9 or to a portion of biglycan and possessing DAPC stabilizing activity. One of ordinary skill in the art would readily understand that the majority of proteins meeting the structural limitation “being at least 80%, 90% or 95% identical to SEQ ID NO: 9, or portion of biglycan” do not meet the functional limitation “comprising DAPC stabilizing activity”. Therefore, it can be concluded that the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant reliance to *In re Wands* is misplaced (page 6, second paragraph of the Response). The instant rejection constitutes a written description rejection and not an enablement rejection, for which *In re Wands* case would be relevant.

6. Claims 1-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. OK

7. Claims 1 and 12-14 are vague and indefinite in so far as they employ the term “biglycan” as a limitation for reasons of record in section 6 of Paper No. 17. Furthermore, claims 1 and 2, as amended, include recitation “or a portion thereof”. It is not clear if a portion of biglycan or a portion of a SEQ ID NO: 9 are intended by the claims. In case a portion of biglycan is recited, the claims stand indefinite for using the term “biglycan” as a limitation without providing structural identification for the term.

8. Claim 13, as amended, is vague and ambiguous for recitation of “the biglycan comprises the amino acid sequences of SEQ ID NOs 1-3”. It is not clear if the biglycan comprises all the recited sequences, only one of the sequences or any combination thereof. Applicant is advised to rewrite the claim in order to better define the claimed subject matter using, for example, the Markush language.

9. Claims 2-11 are indefinite for being dependent from the indefinite claim.

Claim Rejections - 35 USC § 103

10. Claims 7, 8, 10, 11, 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ruoslahti et al. for reasons of record in section 13 of paper No. 17.

Claims 7, 8, 10, 11, 13 and 14 are directed to a method for stabilizing dystrophin-associated protein complexes (DAPCs) on the surface of a cell by contacting the cell with a biglycan of a specific amino acid sequence. Ruoslahti et al. disclose a method for treating a pathology characterized by an accumulation of extracellular matrix in a tissue by contacting said tissue with an agent that suppresses the extracellular matrix producing activity of TGF- β (see the abstract and claim 1), wherein said agent is biglycan (see claim 8).

Applicant submits that “a skilled artisan would not have had a reasonable expectation of success if, for the sake of argument, the Ruoslahti reference were combined with specific biglycan sequences” (page 10, third paragraph of the Response). This statement has been found to be unsubstantiated. On the contrary, one skilled in the art, by reading the disclosure of Ruoslahti et al., which clearly employs a method of contacting biglycan with a tissue, would reasonably expect that as long as a molecule is identified as biglycan, regardless of its precise molecular structure, it can be successfully used in the protocol provided by Ruoslahti et al.. By practicing the protocol of Ruoslahti et al., stabilizing of DAPCs on the surface of a cell is inherently achieved, absent evidence to the contrary. There is no evidence found in prior art, or in publication of Ruoslahti et al., or even in the instant specification, as filed, which would indicate any reasons that particular molecular embodiments of biglycans are expected to possess unique characteristics and, therefore, have to be excluded from the entire genus of biglycan molecules. Therefore, the instant invention, which employs specific sequences of biglycan, is obvious over Ruoslahti et al., which describes a method of using the entire genus of biglycans to achieve the same purpose.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 103

11. Claims 1-6, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruoslahti et al. for reasons explained earlier in section 10 of the instant office action as applied to claims 7, 8, 10, 11, 13 and 14. See also reasoning in section 12 of Paper No. 17.

Claims 1-6, 9 and 12 are directed to a method for stabilizing dystrophin-associated protein complexes (DAPCs) on the surface of a cell by contacting the cell with biglycan, wherein said biglycan has 80% or 90% sequence identity to SEQ ID NO: 9. Briefly, because Ruoslahti et al. describe a method for treating a pathology characterized by an accumulation of extracellular matrix in a tissue by contacting said tissue with an agent that suppresses the extracellular matrix producing activity of TGF- β (see the abstract and claim 1), wherein said agent is biglycan (see claim 8), it would have been *prima facie* obvious for one skilled in the art to use any biglycan in the protocol of Ruoslahti et al. One of ordinary skill in the art would have been motivated to do this because Ruoslahti et al. clearly describe the method of contacting a tissue with biglycan and there is no information available to prevent using certain molecular embodiments of biglycan at the time of the instant invention.

Conclusion

12. No claim is allowed.

13. This application contains claims 15-52 drawn to an invention nonelected with traverse in Paper No. 16. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

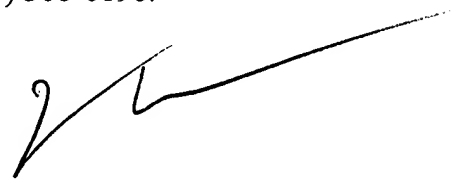
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28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
February 13, 2003



JOHN ULM
PRIMARY EXAMINER
GROUP 1800